

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-55 are in this case. Claims 1-12, 14-15 and 17-55 were withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 13 and 16 have been rejected. Claims 13 and 16 have now been amended.

35 U.S.C. § 112, First Paragraph, Rejections

The Examiner has rejected claims 13 and 16 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention. The Examiner's rejections are respectfully traversed.

The examiner points out that claims 13 and 16 recite the use of "interferon gamma-inducible protein 10" and that this term encompasses a protein derived from any animal species as well as mutants and alleles of this protein.

Applicant disagrees with the Examiner in that the specification does not provide adequate written description with respect to mutants alleles and the like.

By disclosing both human and mouse interferon gamma-inducible protein 10 (IP-10) polypeptide and polynucleotide sequences (by reference to published database sequences) and by providing IP-10 specific primer sequences (see page 71, line 15 of the filed application), the present inventor has in fact provided the ordinary skilled artisan with the tools and guidance necessary for isolating IP-10 sequences from other species.

Although cloning of previously unknown genes can be difficult and time consuming, once a specific gene sequence is cloned, orthologues thereof as well as variants (e.g. splice or allelic variants) can be easily identified and cloned due to the fact that gene-specific sequence can be designed and the fact that molecular tools such as cDNA libraries of various species and tissue types are widely available.

Indeed, a quick scan for IP-10 related information in the GeneCards database (<http://www.rzpd.de/cards/index.shtml>) reveals that an abundance of information is

available for this gene including information relating to orthologues, variants, SNPs and the like.

The Examiner also states that the term "an immunological portion thereof" as defined in the specification "encompasses a massive variety of mutant peptides" that are not disclosed in the specification or known in the prior art.

Applicant agrees with the Examiner that this phrase encompasses a large group of variants, but would like to point out that such a group of sequences is well defined and thus readily recognizable and obtainable by the ordinary skilled artisan. As is well known in the art, an immunological portion of a polypeptide is any portion capable of eliciting an immunological response in a host (e.g. human). Since sequence information relating to IP-10 is available or is readily obtainable as argued above, the artisan would be more than capable of identifying an immunological portion of any IP-10 polypeptide, by, for example, computationally identifying amino acid sequences that form antigenic domains therein (using, for example, EMBOSS <http://www.hku.hk/bruhk/sgpss.html>).

Generation of immunological portions of a polypeptides is analogous to generation of antisense or RNAi sequences. Examiner will agree that in order to generate antisense sequences, one of ordinary skill in the art need only be in possession of the target polynucleotide sequence. Such a target sequence can be utilized to generate a plurality of functional antisense or RNAi sequences by using appropriate software which takes into consideration sequence length and GC composition and various other parameters. Likewise, in generating an immunological portion of a polypeptide, one of ordinary skill in the art need only be in possession of the polypeptide sequence of interest, since such a sequence can be utilized to derive peptide sequences with the desired immunogenicity.

In view of the above arguments, Applicant believes to have overcome the 35 U.S.C. § 112, first paragraph, rejections.

The Examiner has rejected claims 13 and 16 under 35 U.S.C. § 102(b) as being anticipated by Tosato et al. as evidenced by Sportsman et al. The Examiner's rejections are respectfully traversed. Claims 13 and 16 have now been amended.

The Examiner states that Tosato et al. teaches methods of administering IP-10 to humans and that such methods would inherently induce protective immunity against MS.

Applicant disagrees that introduction of IP-10 for the purposes of inhibiting neovascularization as taught by Tosato et al. would inherently produce protective immunity.

As is taught by the instant application, protective immunity necessitates "an amount of interferon gamma-inducible protein 10, or an immunological portion thereof, sufficient to elicit sufficient anti-interferon gamma-inducible protein 10 antibodies so as to break-down the immunological tolerance to interferon gamma-inducible protein 10" (page 32, lines 7-11). As is detailed in page 56, lines 9-15, the instant application provides the guidance necessary for quantifying such an amount.

It should be noted that contrary to the Examiners assessment, Tosato et al. do not teach administration of IP-10 amounts which would lead to protective immunity, since the method of Tosato et al. relies upon IP-10 activity, and as such, any downregulation of such activity which would result from formation of anti-IP-10 antibodies would in fact be counter productive to the effect desired by Tosato et al.

Notwithstanding from the above and in the interest of expediting prosecution of this case, Applicant has elected to amend claims 13 and 16 to further distinguish the claimed invention from the teachings of Tosato et al. Thus, claims 13 and 16 have now been amended to include the phrase "a subject in need thereof" (page 45, line 18) clearly identifying the subject treated as that suffering from, or being predisposed to, MS.

Since the treatment method disclosed by Tosato et al. targets individuals with disorders associated with neovascularization, e.g., tumors, the teachings thereof do not in any way suggest IP-10 administration for the purpose of treating individuals having, or being predisposed to MS.

In view of the above amendments and remarks it is respectfully submitted that claims 13 and 16 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Martin D. Moynihan

Martin Moynihan,
Registration No. 40,338

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Enc.:

Two month extension fee